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From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

H IBERG A/S  
St. Kongensgade 59A  
DK-1264 Copenhagen K  
DANEMARKRECEIVED  
25 OKT. 2004  
HØIBERGNOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing  
(day/month/year)

21.10.2004

Applicant's or agent's file reference  
P688PC00

## IMPORTANT NOTIFICATION

International application No.  
PCT/DK 03/00686International filing date (day/month/year)  
10.10.2003Priority date (day/month/year)  
11.10.2002Applicant  
CARTIFICIAL A/S et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

## 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

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preliminary examining authority:European Patent Office  
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# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P688PC00	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/DK 03/00686	International filing date (day/month/year) 10.10.2003	Priority date (day/month/year) 11.10.2002
International Patent Classification (IPC) or both national classification and IPC A61L27/44		
Applicant CARTIFICIAL A/S et al.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand  10.05.2004	Date of completion of this report  21.10.2004	
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Pilling, S  Telephone No. +49 89 2399-8461 	

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/DK 03/00686

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-49 as originally filed

**Claims, Numbers**

1-101 as originally filed

**Drawings, Sheets**

1/8-8/8 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/DK 03/00686

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	1,56
	No: Claims	
Inventive step (IS)	Yes: Claims	1,56
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1,56
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

**Re Item V****Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. The documents cited in the International Search Report (ISR) are consecutively numbered D1 to D6 in the order of their listing. If not indicated otherwise, reference is made to the passages cited in said ISR.
2. None of the presently available prior art documents disclose a medical device comprising the layered structure defined in either present Claim 1 or Claim 56. Thus, the subject matter of Claims 1 and 56 is new (Article 33(2) PCT).
3. The closest prior art in respect of Claims 1 and 56 appears to be document D1 since this document discloses a biocompatible prosthetic device for insertion into a joint cavity comprising a first polymeric component and a second shorter chain length polymeric component (see page 2 lines 2 to 7 in D1). There appears to be no clear teaching in this document however, towards a layered structure as defined in present Claims 1 and 56 and this document may even be considered as teaching away from the use of a layered structure (see page 10 lines 25 to 28). Thus, the solution of improving the wear resistance, strength and toughness of a prosthetic device by using the layered structure defined in Claims 1 and 56 does not appear to be obviously derivable from the disclosure of document D1 without using inventive skill.
4. Thus, the subject matter of Claims 1 and 56 appears to be inventive (Article 33(3) PCT).